REMARKS

Claims 10-12, 40-43, 45-48 and 50-55 are currently pending in this application, and stand rejected. Applicants respectfully request entry of the above amendments and reconsideration and allowance of claims 10-12, 40-43, 45-48 and 50-55, as amended.

Amendments to the Claims

Claims 10 and 46 have been amended by addition of the term "female" prior to the phrase "sexual arousal disorder." Support for this amendment is in the specification as originally filed. No new matter is added by this amendment.

35 U.S.C. § 103(a) Rejection of Claims 10-12, 40-43, 45-48 and 50-55

Claims 10-12, 40-43, 45-48 and 50-55 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Kaplan et al., Urology, 1999, 53(3), 481-486 (hereinafter referred to as "Kaplan"). The final office action also refers to the Place et al. reference (U.S. Patent 6,306,841, issued October 23, 2001, hereinafter referred to as "Place"). It is unclear to applicants' representative whether the rejection is based on Kaplan alone, Place alone or the combination of Kaplan and Place and therefore all of these possible grounds of rejection will be addressed.

Claims 10-12, 40-43, 45-48 and 50-55 Are Non-Obvious in View of Kaplan

The Examiner has alleged that "Kaplan et al teach the safety and efficacy of sildenafil in post-menopausal woman for treating sexual dysfunction (title). Oral delivery is disclosed (p. 485 first full paragraph)." Applicants respectfully traverse.

Applicants submit that, contrary to the Examiner's assertion, Kaplan does not teach or suggest the efficacy of sildenafil in treating female sexual dysfunction, particularly sexual arousal disorder, in postmenopausal women.

Applicants agree that Kaplan teaches oral administration of sildenafil in postmenopausal women. Kaplan describes a single dosage level non-placebo controlled study of sildenafil that showed that sildenafil was well tolerated in postmenopausal women with sexual dysfunction. Kaplan states that "Overall sexual function did not improve significantly, although there were changes in vaginal

lubrication and clitoral sensitivity. The role of sildenafil in treating sexual dysfunction in various cohorts of women remains to be determined." (Kaplan at 481, lines 20-24). Kaplan further states that "Our data do not support the use of sildenafil in treating postmenopausal women with sexual dysfunction." (Kaplan at 483, right column, last paragraph). In addition, Kaplan indicates that combination therapy with certain agents is speculative in nature and has yet to be investigated by posing the question "What is the potential role of combining various oral agents (i.e. an alpha-blocker with either sildenafil or apomorphine)?" (Kaplan at 485, left column, lines 5-13).

Kaplan makes no mention whatsoever of the use of an estrogen agonist/antagonist either alone or in combination with sildenafil for treating female sexual arousal disorder as instantly claimed. Furthermore, Kaplan does not suggest in any way the combined use of an estrogen agonist/antagonist and sildenafil but instead points out that the role of combination therapy with other oral agents (not sildenafil) for treating female sexual dysfunction remains to be addressed. Applicants respectfully submit that Kaplan in no way teaches or suggests the instantly claimed method and thus claims 10-12, 40-43, 45-48 and 50-55 are non-obvious in view of Kaplan.

Claims 10-12, 40-43, 45-48 and 50-55 Are Non-Obvious in View of Place

In rejecting claims 10-12, 40-43, 45-48 and 50-55 under 35 U.S.C. 103(a) the Examiner has relied on Place et al. (U.S. Patent 6,306,841, issued October 23, 2001, hereinafter referred to as "Place"). The Examiner has alleged that Place teaches a composition for treating female sexual dysfunction and that estrogen antagonists such as tamoxifen, raloxifene and centchroman are disclosed. The Examiner further states that Place teaches the treatment of dyspareunia both pre- and post-menopausally. Applicants respectfully traverse.

Applicants presently claim a method of treating sexual arousal disorder in a female by oral administration of an estrogen agonist/antagonist, and oral co-administration of a cyclic guanosine 3', 5'-monophosphate elevator. Place discloses local administration of various combinations of vasoactive agents with other classes of agents. Local administration includes vaginal, vulvar or urethral administration. Place

discloses numerous possible combinations of vasoactive agents with other classes of agents for administration to the vagina, vulvar area or urethra.

Place does not provide or suggest each of the elements of the presently claimed invention. The method of instant claims 10-12, 40-43, 45-48 and 50-55 requires oral administration of the estrogen agonist/antagonist and cyclic guanosine 3', 5'-monophosphate elevator for treating female sexual arousal disorder. The method of Place requires that a vasoactive agent is administered by "vaginal delivery", "vulvar delivery", or "urethral delivery" (see Place at column 4, lines 32-36; column 5, lines 65-67 and column 6, lines 1-19). Place does not disclose or suggest any method whatsoever of oral administration of a pharmaceutical composition and makes no mention of oral administration of an estrogen agonist/antagonist, and oral co-administration of a cyclic guanosine 3', 5'-monophosphate elevator to treat sexual arousal disorder as instantly claimed.

Second, Place does not disclose or suggest the instantly claimed method employing the combination of an estrogen agonist/antagonist and a cyclic guanosine 3', 5'-monophosphate elevator as in instant claims 10-12, 40-43, 45-48 and 50-55. Place generically discloses numerous possible combinations of vasoactive agents with other classes of agents for administration to the vagina, vulvar area or urethra. However, Place makes no specific disclosure of use of a combination of an estrogen agonist/antagonist and a cyclic guanosine 3', 5'-monophosphate elevator in the methods therein. Particularly, with respect to claims 47-48, Place does not disclose or suggest the method employing the specific combination comprising the compound (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol. Since Place does not disclose or suggest the elements required in the present method of treating sexual arousal disorder by oral administration of an estrogen agonist/antagonist along with oral co-administration of a cyclic guanosine 3', 5' monophosphate elevator, Place thus does not render obvious the instant method of claims 10-12, 40-43, 45-48 and 50-55.

Accordingly, one of ordinary skill in the art, in view of Place and employing ordinary creativity and exercising common sense would not arrive at the instant method of claims 10-12, 40-43, 45-48 and 50-55. There is no motivation intrinsic to Place to arrive at the present method of claims 10-12, 40-43, 45-48 and 50-55. Place

never mentions oral administration of an estrogen agonist/antagonist together with a cyclic guanosine 3',5'-monophosphate elevator. Thus, there is no suggestion in Place to use oral administration of an estrogen agonist/antagonist in combination with a cyclic guanosine 3',5'-monophosphate elevator to treat sexual arousal disorder in females. Furthermore, Place does not provide motivation to one of ordinary skill in the art to select certain estrogen agonist/antagonists that are not disclosed in Place and then combine them with a cyclic guanosine 3',5'-monophosphate elevator and then modify the vaginal, vulvar or urethral administration method of Place to arrive at the method of instant claims 10-12, 40-43, 45-48 and 50-55.

Applicants respectfully submit that a person of ordinary skill in the art would not be expected to make the specific changes to Place required to arrive at the instant invention. In view of this, Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. 103(a) rejection of claims 10-12, 40-43, 45-48 and 50-55.

Claims 10-12, 40-43, 45-48 and 50-55 Are Non-Obvious in View of the Combination of Kaplan and Place

The Examiner has alleged that it would be obvious to one of ordinary skill in the art to add a steroid antagonist to the orally delivered sildenafil in the method of Kaplan to achieve an additional beneficial effect for treating sexual dysfunction.

Applicants respectfully submit that a proper combination of Kaplan and Place does not provide the instantly claimed method of treating female sexual arousal disorder. Place does not teach or suggest treatment of female sexual arousal disorder by oral administration of an estrogen agonist/antagonist and oral co-administration a cyclic guanosine 3',5'-monophosphate elevator as discussed above. The method of Kaplan showed that oral administration of sildenafil in postmenopausal women was well tolerated but Kaplan stated that "Our data do not support the use of sildenafil in treating postmenopausal women with sexual dysfunction." (Kaplan at 483, right column, last paragraph). Kaplan is a report on safety and efficacy but does not conclude that the method described is effective.

One of ordinary skill in the art, employing ordinary creativity and common sense would not be motivated to modify the method of Kaplan to arrive at the instantly claimed method since there is clearly no motivation or suggestion to do so in that reference. One of ordinary skill in the art, in view of Kaplan, would not be motivated to modify the method disclosed therein to arrive at the instantly claimed method since there is no reasonable expectation of success in doing so. Furthermore, Place does not provide that motivation since Place does not disclose or suggest any method of oral administration of agents for treating sexual arousal disorder as instantly claimed. Even if Kaplan and Place are combined one does not arrive at the instantly claimed method. Combination of Kaplan and Place would provide a method in which sildenafil is administered orally and any of numerous combinations of vasoactive agents with other classes of agents would be administered to the vagina, vulvar area or urethra. Thus, the combination of Kaplan and Place does not provide the instantly claimed method and therefore the instantly claimed method is non-obvious in view of the combination of Kaplan and Place. In view of this, Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. 103(a) rejection of claims 10-12, 40-43, 45-48 and 50-55.

Conclusion

Applicants believe that, in view of remarks made above, this application is in condition for allowance. Reconsideration and allowance of claims 10-12, 40-43, 45-48 and 50-55, is respectfully requested.

Respectfully submitted,

Date: 1 February 2008

/ John A. Wichtowski /
John A. Wichtowski
Attorney for Applicant(s)
Reg. No. 48,032

Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860)715-6645